

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) Microparticulate oral pharmaceutical dosage form for the delayed and controlled release of at least one active principle (AP) -- excluding perindopril -- this active principle having an absorption window in vivo that is essentially limited to the upper parts of the gastrointestinal tract,

wherein the dosage form comprises "reservoir" microcapsules of active principle, each coated with one single, composite coating film,

wherein the single, composite coating film comprises at least one hydrophilic polymer A carrying groups that are ionized at neutral pH, and at least one hydrophobic compound B;

wherein the at least one hydrophobic compound B is selected from the group consisting of hydrogenated vegetable oils, vegetable waxes, wax yellow, wax white, wax microcrystalline, lanolin, anhydrous milk fat, hard fat suppository base, lauroyl macroglycerides, cetyl alcohol, polyglyceryl diisostearate, ~~monoester or diester~~ or triester of glycerol with at least one fatty acid, ~~taken by themselves or in mixture with one another,~~ and mixtures thereof;

wherein the microcapsules have a diameter of between 200 and 800 microns;

wherein the weight ratio B/A is between 0.5 and 1.5; ~~and~~

wherein the release of the active principle is governed by two different triggering mechanisms,

wherein the first triggering mechanism releases the at least one active principle based on a variation in pH, ~~and~~

wherein the second triggering mechanism releases the at least one active principle after a predetermined residence time in the stomach, and

wherein the dissolution behavior of the pharmaceutical dosage in vitro is such that:

at a constant pH of 1.4, the dissolution profile includes a latency phase with a duration less than or equal to 5 hours, and a controlled release phase following the latency phase such that the release time for 50% of the active principle ($t_{1/2}$) is between 0.5 hour and 35 hours, and

the change from pH 1.4 to pH 6.8 results in a release phase that starts without a latency period.

2. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the dissolution profile includes a latency phase with a duration of between 1 and 5 hours.

3. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the mass fraction of the coating film (% by weight, based on the total mass of the microcapsules) is less than or equal to 40.

4. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the weight ratio B/A is between 0.5 and 1.0.

5. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the at least one hydrophilic polymer A is selected from the group consisting of: (meth)acrylic acid polymers, alkyl (meth)acrylate polymers, (meth)acrylic acid/alkyl (meth)acrylate copolymers, cellulose derivatives, cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate; and mixtures thereof.

6. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the at least one hydrophilic polymer A is selected from the group consisting of: (meth)acrylic acid/ methyl(meth)acrylate copolymers, cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate, hydroxypropyl methyl cellulose acetate succinate; and mixtures thereof.

7. (Canceled)

8. (Canceled)

9. (Currently Amended) The pharmaceutical dosage form according to claim 1, wherein said hydrophobic compound B is selected from the group consisting of: hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, Carnauba wax, tristearin, tripalmitin, trimyristin, glyceryl palmitostearate, glycerylstearate, ~~diethylene glycol monostearate, ethylene glycol monostearate,~~ and any mixtures thereof.

10. (Previously Presented) The pharmaceutical dosage form according to claim 9, wherein said hydrophobic compound B is selected from the group consisting of: hydrogenated cottonseed oil, hydrogenated soybean oil, hydrogenated palm oil, glyceryl behenate, hydrogenated castor oil, tristearin, tripalmitin, trimyristin and any mixtures thereof.

11. (Canceled)

12. (Canceled)

13. (Previously Presented) The pharmaceutical dosage form according to claim 1 wherein the coating film of the microcapsules is free from talc.

14. (Canceled)

15. (Previously Presented) The pharmaceutical dosage form according to claim 1, characterized in that the release phase following the change from pH 1.4 to pH 6.8, which takes place without a latency period, is such that the release time for 50% of the active principle ($t_{1/2}$) is defined as follows (in hours): $0.25 \leq t_{1/2} \leq 20$.

16. (Canceled)

17. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the active principle is deposited on a neutral core with a diameter of between 200 and 600 microns.

18. (Previously Presented) The pharmaceutical dosage form according to claim 17, wherein the neutral core contains sucrose or dextrose or lactose.

19. (Previously Presented) The pharmaceutical dosage form according to claim 17, wherein the neutral core is a cellulose microsphere.

20. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein the at least one active principle is selected from the group consisting of: antiulcer agents, antidiabetics, anticoagulants, antithrombics, hypolipidemics, antiarrhythmics, vasodilators, antiangina agents, antihypertensives, vasoprotectors, fertility promoters, labor inducers and inhibitors, contraceptives, antibiotics, antifungals, antivirals, anticancer agents, anti-inflammatories, analgesics, antiepileptics, antiparkinsonian agents, neuroleptics, hypnotics, anxiolytics, psychostimulants, antimigraine agents, antidepressants, antitussives, antihistamines and antiallergics.

21. (Previously Presented) The pharmaceutical dosage form according to claim 20, wherein the active principle is selected from the group consisting of amoxicillin, metformin, acetylsalicylic acid, pentoxifyllin, prazosin, acyclovir, nifedipine, diltiazem, naproxen, ibuprofen, flurbiprofen, ketoprofen, fenoprofen, indomethacin, diclofenac, fentiazac, estradiol valerate, metoprolol, sulpiride, captopril, cimetidine, zidovudine, nicardipine, terfenadine, atenolol, salbutamol, carbamazepine, ranitidine, enalapril, simvastatin, fluoxetine, alprazolam, famotidine, ganciclovir, famciclovir, spironolactone, 5-asa, quinidine, morphine, pentazocine, paracetamol, omeprazole, metoclopramide and mixtures thereof.

22. (Previously Presented) The pharmaceutical dosage form according to claim 1, wherein said pharmaceutical dosage form is selected from the group consisting of: a tablet, a powder and a capsule.

23. (Canceled)

24. (Previously Presented) The pharmaceutical dosage form according to claim 1 which is a tablet that disperses in the mouth.